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	Title CIP Inspection Process		Page 1 of 3
	Process Owner CIP Management Analyst		Approval Authority Head, CIP Department

1. Purpose & Scope

This process defines the method of scheduling, preparing, performing, and reporting annual CID inspections.

2. References

The following documents are either required or helpful to perform the set of tasks in the accompanying flowchart; a) NSHS-001, NSHS Quality Manual, b) NSHS-002, Quality Systems Document Control, c) NSHS-004 Corrective & Preventive Action, d) BUMEDINST 6000.12 series.

3. Definitions

The terms listed below are defined to assist the reader.

- 3.1 **Clinical Investigation Department (CID)**: Each CID will act as local or regional program manager for clinical investigations within its area of responsibility. The Commander/Commanding Officer of each medical treatment facility and dental treatment facility with a CID has responsibility for the implementation of his/her local program.
- 3.2 **Clinical Investigation Program (CIP)**: The system of directives, offices, and personnel that enable clinical research within the Department of the Navy.
- 3.3 **IRB**: Institutional Review Board.

4. Document Review & Concurrence

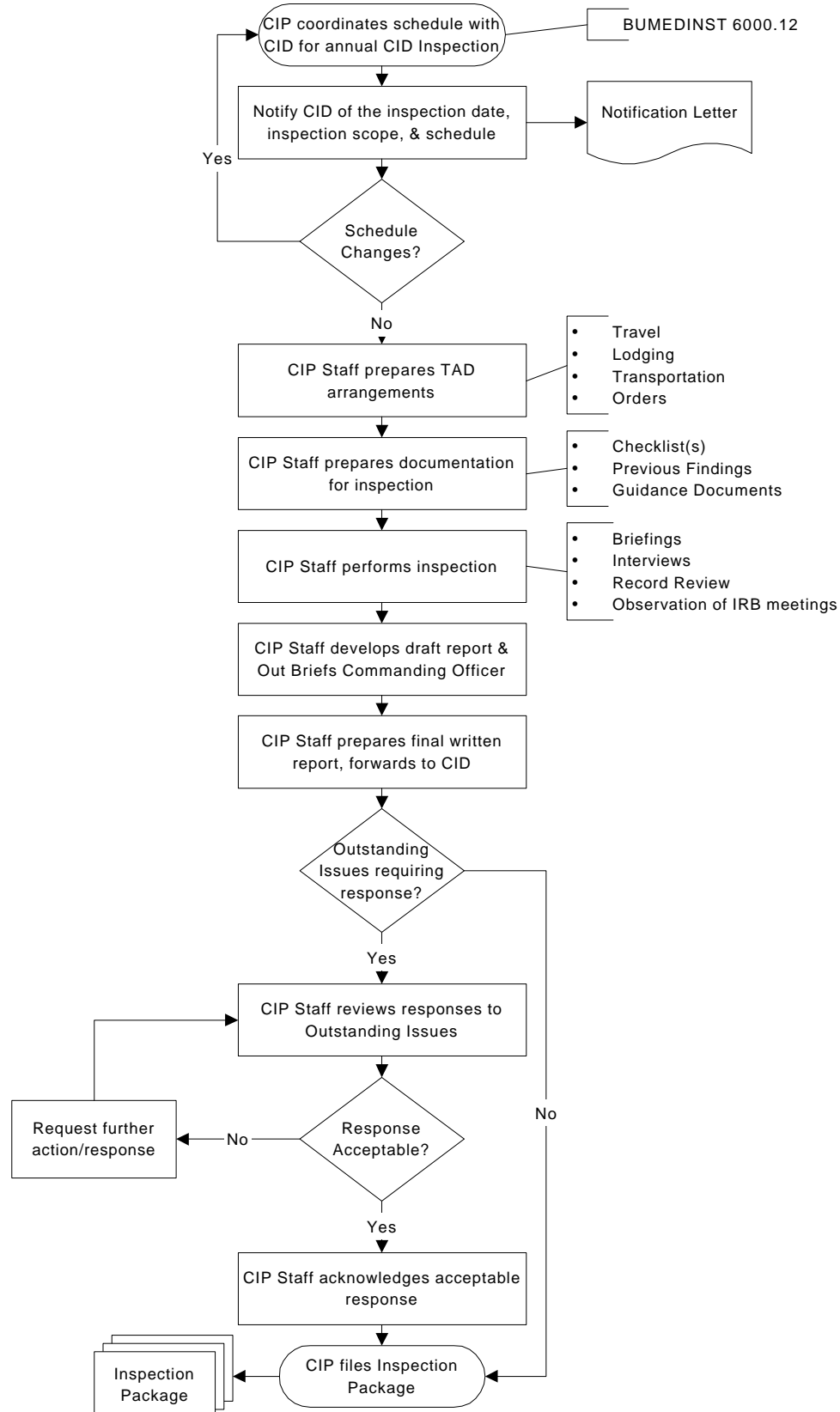
Title of Reviewer	Functional Directorate	Signature & Date	Title of Reviewer	Functional Directorate	Signature & Date
Management Analyst	OP6 (Process Owner)	Ms. E. Cooper	Head, CIP Department	OP6 (Approval Authority)	CAPT P. Kent

5. Summary of Changes

Version	Description	Date
01	Initial issue of procedure.	17 MAY 01

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6. Process Flowchart



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7. Quality Records

<i>Record Name</i>	<i>Owner</i>	<i>Location</i>	<i>Indexing</i>	<i>Duration</i>	<i>Disposition</i>
Inspection Package	Management Analyst	File Cabinet	By FY	Permanent	Permanent

8. Addendum

N/A